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510(k) SUMMARY

V.A.C. Simplicity™ Negative Pressure Wound Therapy Unit

Date prepared	July 20, 2011
510(k) owner	KCI, Inc.
Name	KCI USA, Inc. (Kinetic Concepts, Inc.)
Address	6203 Farinon Drive; San Antonio, Texas 78249
Fax number	210 255-6727
Name of contact person	Margaret Marsh
Contact telephone number	1 800 275-4524; Request Regulatory Affairs.
Name of the device	
Trade or proprietary name	V.A.C. Simplicity™ Negative Pressure Wound Therapy Unit
Common or usual name	Negative Pressure Wound Therapy Unit
Classification name	Negative Pressure Wound Therapy Powered Suction Pump
Legally marketed device(s) to which equivalence is claimed	ActiV.A.C.® Negative Pressure Wound Therapy Unit, cleared under 510(k) K06369
Device description	Negative pressure wound therapy unit component of an integrated negative pressure wound therapy system
Device design	The therapy unit is nearly identical to the predicate product, except for the user interface, which is similar to that of the currently marketed V.A.C. Via Therapy Unit. The therapy unit delivers negative pressure wound therapy to the wound bed through the V.A.C. ® Foam Dressing System; it also transfers wound exudates into a canister. Software monitors and maintains target pressure and alarms as needed to help assure target pressure is maintained and constant therapy is delivered. The safety features of the system include alarms, such as those that signal for blockages, low battery, and leaks in the system.

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<table>
<tr><td>Intended use of the device</td><td colspan="3">The V.A.C. Simplicity™ Therapy System is an integrated wound management system for use in acute, extended and home care settings. It is intended to create an environment that promotes wound healing by secondary or tertiary (delayed primary) intention by preparing the wound bed for closure, reducing edema, promoting granulation tissue formation and perfusion, and by removing exudate and infectious material. It is indicated for patients with chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic, pressure or venous insufficiency), flaps and grafts</td></tr>
<tr><td>Differences in intended use from the predicate(s)</td><td colspan="3">The intended use is identical to that of the predicate.</td></tr>
<tr><td rowspan="5">Summary of the technological characteristics of the device compared to the predicate device</td><td>Feature</td><td>V.A.C. Simplicity™ Therapy System</td><td>ActiV.A.C. Therapy System</td></tr>
<tr><td>Therapy unit</td><td>Same as predicate</td><td>Software controlled pump for delivery of negative pressure wound therapy</td></tr>
<tr><td>Therapy options</td><td>-125 mmHg only</td><td>Selectable negative pressure settings in the range of -25 to -200 mmHg.</td></tr>
<tr><td>Dressing system</td><td>Same as predicate</td><td>Foam based dressing with occlusive drape</td></tr>
<tr><td>Pressure sensing</td><td>Same as predicate</td><td>By means of a sensing pad in tubing line</td></tr>
<tr><td>Summary of nonclinical tests</td><td colspan="3">The V.A.C. Simplicity™ Therapy Unit was evaluated to assure conformance to design specifications.
The following bench tests were conducted:
• Ability to deliver NPWT at -125 mmHg in a comparable manner to the ActiV.A.C. Therapy Unit. Testing demonstrated that the V.A.C. Simplicity™ Therapy Unit delivers equivalent negative pressure wound therapy at -125 mmHg.
• Software verification and validation testing confirms that the software meets the requirements of the software requirements specification.
• The therapy unit was tested to all applicable electrical safety and electromagnetic emissions standards and was found to be in compliance.</td></tr>
<tr><td>Summary of clinical tests</td><td colspan="3">Although human clinical studies were not required to be conducted, usability studies were performed with 30 subjects representing home care nurses and patients to assure that the product could easily be used in the home environment and that labeling can be understood and followed.
KCI previously conducted simultaneous usability testing on home</td></tr>
</table>

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	care and extended care nurses for a similar product, the V.A.C. Via Negative Pressure Wound Therapy Unit. This testing validated that the results from home care nurses are equivalent to extended care nurses, in that they responded in an identical manner throughout the usability testing. Based on this experience, the home care nurse responses in the V.A.C. Simplicity™ Therapy Unit usability test are supportive of usability in the extended care environment.
Conclusions drawn from the nonclinical and clinical tests that demonstrate that the device is as safe, as effective, and performs as well as or better than the predicate device	Testing demonstrates that the V.A.C. Simplicity™ Therapy Unit is substantially equivalent in terms of both indications for use and technology to the predicate product

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

KCI USA, Inc.
% Ms. Margaret Marsh
Regulatory Affairs Technical Director
6203 Farinon Drive
San Antonio, Texas 78249-3441

JUL 2 1 2011

Re: K111280
Trade/Device Name: V.A.C. Simplicity™ Negative Pressure Wound Therapy System
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered suction pump
Regulatory Class: II
Product Code: OMP
Dated: May 2, 2011
Received: May 6, 2011

Dear Ms. Marsh:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number K111280
Device Name: V.A.C. Simplicity™ Negative Pressure Wound Therapy System

Indications for Use:

The V.A.C. Simplicity™ Negative Pressure Wound Therapy System is an integrated wound management system for use in acute, extended and home care settings. It is intended to create an environment that promotes wound healing by secondary or tertiary (delayed primary) intention by preparing the wound bed for closure, reducing edema, promoting granulation tissue formation and perfusion, and by removing exudate and infectious material. It is indicated for patients with chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic, pressure or venous insufficiency), flaps and grafts.

Prescription Use ____X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause for MKM

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K111280

(Posted November 13, 2003)